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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/868,261 | 10/05/2001 | John P. McKearn | CU-2563 RJS | 7559 |

7590

03/26/2003

Mr. James M. Warner
Assistant General Counsel - Pharmacia Corporation
Global Patent Department
800 North Lindbergh Blvd.,
St. Louis, MO 63167

| EXAMINER | |
|--------------------|--------------|
| GOLDBERG, JEROME D | |
| ART UNIT | PAPER NUMBER |
| 1614 | |

DATE MAILED: 03/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/868,261

Applicant(s)

MCKEARN ET AL.

Examiner

Jerome D Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-144 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-144 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Restriction to one of the following inventions is required under 35 U.S.C. 121.

Group I: claims 1-55, 112-137 and 142 drawn to methods and compositions for treating tumors employing an enhanced combination of a cyclooxygenase-2 inhibitor, an integrin antagonist and an antineoplastic agent.

Group II: claims 56-111 and 138-140 drawn to methods for treating tumors employing an enhanced combination of radiation ~~alone~~ with the group I combination.

Group III: claims 141 and 144 drawn to methods for treating tumor employing an enhanced combination of a cyclooxygenase-2 inhibitor and an integrin antagonist.

Group IV: claim 143 drawn to a method for treating tumors employing radiation with the enhanced combination of group III.

Applicants state on page 12, last three lines that the "inventions are administered in combination at a low dose, that is, at a dose lower than has been conventionally used in clinical situations."

If applicants elect groups I -IV, applicants are, therefore, required to elect a single enhanced combination of one cyclooxygenase-2 inhibitor with one integrin antagonist with or without one antineoplastic agent. The neoplastic agents are classified in both class 514 and class 424. For example, cisplatin is in class 424 subclass 649, doxorubicin is in class 514, subclass 34 and paclitaxel is in class 514, subclass 449.

The several inventions above are independent and distinct, each from the other, as they have acquired a separate status in the art of treating tumors as a separate

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subject matter for inventive effect and require independent searches. It is noted that a reference to one enhanced combination of drugs under 35 U.S.C. 103. Further, the claims read on a multitude of enhanced combinations of drugs which would require many field of searches that would be an undue burden on the Examiner. Therefore, restriction for examination purposes is proper.

Applicants are required to make a provisional election even though this requirement is traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerome Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday-Thursday 9:00 A.M - 3:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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Goldberg/tgd
March 24, 2003

A handwritten signature in black ink, appearing to read 'J.D. Goldberg', with a long, sweeping horizontal stroke extending to the right.

JEROME D. GOLDBERG
PRIMARY EXAMINER